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Participant Information Sheet & Consent Form – Dialyse@home: A Mixed Methods Pilot Study of Home Haemodialysis (Carer)

You are being invited to take part in a research project. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

1. What is the purpose of the study?

This study aims to explore the impact of home haemodialysis on patient and carer experience, and wider support needs. It will also explore which factors influence the interest that patients might have in dialyzing at home, and the best ways to help people to feel supported when they are dialyzing at home.

2. Why have I been chosen?

You have been invited to take part because you are a carer for a person who is treated with home haemodialysis.

3. Do I have to take part?

No. It is up to you whether or not you take part. You can stop at any time without giving a reason. If you wish to withdraw consent please speak to your local study investigator (details at the bottom of this information sheet).

4. What do I have to do?

This is a study that only involves the completion of a single questionnaire, and if you agree, interviews.

If you agree, please complete the questionnaire that is with this information sheet including the consent page. Once you have completed it, please return the consent form and questionnaire in the enclosed stamped addressed envelope. We think the questionnaire will take about 5 minutes to complete.

As part of the study, a deeper investigation into home haemodialysis treatment will be carried out using interviews with a small number of patients and carers. You will be sent information about how to participate in this part of the study should you wish to separately.

5. What are the possible benefits of taking part?

There will be no direct benefit to you from taking part. However, the study will give information that will help us to better understand and possibly improve treatment for kidney patients and their carers.

6. What are the possible disadvantages of taking part?

There is no physical risk to you from this study. If you find the questionnaire raises any sensitive issues you may feel it is important to discuss these. If you would like support after completing the questionnaire a member of the research team will be available by telephone or in person.

7. What if something goes wrong?

We do not expect anything to go wrong as this study is only collecting information.
If you have any concerns about any aspect of this study, in the first instance you should speak to the local study investigator at your site, who will do their best to answer your questions. You can also contact the Chief Investigator for the whole study (Prof. Martin Wilkie, Sheffield Teaching Hospitals NHS Foundation Trust). Contact details are at the end of this information sheet. If you feel that your concern has not been adequately dealt with, then please contact the Patient Advice and Liaison Service at your hospital.

8. Will my part in this study be kept secret?

All information collected about you as a result of your participation in the study will be kept strictly confidential, and will be used for the purposes of this research only.
Your completed questionnaire will be kept in a highly secure server within the Sheffield Teaching Hospitals NHS Foundation Trust and the University of Sheffield, and will be handled securely in accordance with the data protection law(s) to ensure that all information about you is handled in the strictest confidence. As part of this study your data will be shared with the UK Renal Registry but not with any third parties not directly involved with this research.
Once you have agreed to participate in this study you will be allocated a unique study number which will be used on all your study documentation. All information will be treated in the strictest confidence during the review process. Your data will be retained for 3 years after which it will be destroyed.

General Data Protect Regulation (GDPR) statement.
Sheffield Teaching Hospital NHS Foundation Trust is the sponsor for this study based in United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it

properly. Sheffield Teaching Hospital NHS Foundation Trust will keep identifiable information about you for 3 years after the study has finished.

Your Hospital Trust [insert name] will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Sheffield Teaching Hospitals NHS Foundation Trust and regulatory organisations may look at your research records to check the accuracy of the research study. [NHS site] will pass these details to Sheffield Teaching Hospital NHS Foundation Trust along with the information collected from you. The only people in Your Hospital Trust [insert name] who will have access to information that identifies you will be people who need to contact you to audit the data collection process. The people who analyze the information will not be able to identify you and will not be able to find out your name, hospital number or contact details.

Sheffield Teaching Hospital NHS Foundation Trust will collect information about you for this research study from the questionnaires that you complete. This information will include name, NHS Number, date of birth, post code and health information, which is regarded as a special category of information. We will use this information to answer the research question.

Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.

9. What will happen to the results of the research study?

Study results are published about large groups of participants. Your individual information will not be shared with the public. The results of the study will be published in journals and at conferences and will contribute to the development or further research studies. If you would like to be informed of the results of the study, please complete your details at the bottom of this sheet.

10. Who is organizing and funding the research?

This study is funded by grant from the Sheffield Hospitals Charity and the Health Foundation.

11. Who has reviewed the study?

This study has been reviewed by the Yorkshire & Humber – South Yorkshire Research Ethics Committee (Ref: 18/YH/0137).

12. What if I am worried?

If you have any questions or want to report any problems with this study, please contact:

Study local investigator

Name:_____ Telephone:_____

If you want independent advice, please contact the Patient Advice and Liaison Service (PALS):

Name:_____ Telephone:_____

Study Chief Investigator

Professor Martin Wilkie, Sheffield Teaching Hospitals NHS Foundation Trust. Tel 01142715326

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CONSENT FORM

Dialyse@home Carer Consent

Name of Researcher: Participant Number:

If you agree with each sentence below, please initial the box.		Initials
1	I confirm that I have read the information sheet dated 10-JUL-18 (version 1.4) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.	
3	I agree that a copy of my consent form with my name and signature can be kept by Sheffield Teaching Hospitals during the study period and for 3 years after the study has ended, that is until 30th June 2021.	
4	I agree to take part in the above study.	

_____ _____ _____

Name of Participant Signature Date

_____ _____ _____ ____:____

Name of Person taking consent Signature Date (24 hour clock)

If you would like to be informed of the results of the study, please complete your contact details below:

Name: _____

Address: _____

_____

_____

Email address: _____

1 copy for the patient, 1 copy for the study team, 1 copy to be retained in the hospital notes

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